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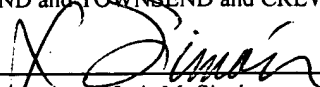
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Alexandria, VA 22313-1450

On: May 24, 2004

TOWNSEND and TOWNSEND and CREW LLP

By:

  
Lois M. Simón

PATENT  
Docket No.: 02558B-063100US  
Client Ref. No.: BRP00064

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michael I. Watkins et al.

Application No.: 09/548,883

Filed: April 13, 2000

For: MULTI-ANALYTE DIAGNOSTIC  
TEST FOR THYROID DISORDERS

Examiner: Gabel, G.

Art Unit: 1641

RESPONSE TO OFFICE ACTION -  
REQUEST FOR RECONSIDERATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Office Action of March 25, 2004, Applicants respectfully request reconsideration and reexamination of this Application on the basis of the accompanying documents and the remarks made herein.

Claims 1-5, 7-22 and 26-28 stand rejected as obvious over combinations of PCT application WO 99/26067 and various secondary references.

The examiner has withdrawn rejections based on the co-owned US patent 6,280,618 due to the co-ownership of this invention with the patent at the time the

invention was made. Applicants state that the stated co-ownership extended to all matters claimed in this Application.

WO 99/26067 is the corresponding published PCT application to this U.S. patent. It is a reference in its own right, however, with an effective date of May 27, 1999, which is less than one year before the filing date of the instant Application.

By accompanying papers, Applicants are correcting the inventorship of this Application by adding Richard B. Edwards as an inventor. Dr. Edwards and Dr. Michael Watkins are the two inventors of the inventions described and claimed in US patent 6,280,618 and in WO 99/26067. Dr. Watkins is also a named inventor in the instant Application. As stated in the previous response with respect to US patent 6,280,618, WO 99/26067 and any comments contained in it about the applicability of the information therein to testing for thyroid conditions represents work of inventors of this Application that was published less than one year prior to the filing date of this Application, and thus is not prior art under either subsection (a) or (b) of 35 U.S.C. 102.

Applicants respectfully request the withdrawal of all rejections of claims in this application, since all are based on WO 99/26067 as the primary reference.

In addition, Applicants again submit that the combinations of references proposed by the examiner do not render the present claims obvious. Applicants understand that when a combination of references is used to reject claims, discussion of the individual references taken alone may not be sufficient to overcome the rejection. However, in discussing the references, Applicants were commenting on what, if any, information of relevance was added to the primary reference by the secondary ones. Applicants submit that for the reasons previously mentioned, the secondary references lack relevance to the disclosure of WO 99/26067 and to the invention claimed herein.

In the previous rejections, the examiner chose to utilize secondary references for certain teachings, without taking sufficient cognizance of the fact that those teachings were contained in a certain context that had certain limitations.

For example, the examiner wishes to utilize a statement in Dietzen et al. that thyroid function study requires accurate assessment of all of TSH, T<sub>3</sub> and T<sub>4</sub>. The examiner wishes to further state that this same statement includes the concept that this should be done in a simultaneous multiple thyroid related analyte binding assay. However, that approach overlooks the fact that Dietzen et al do not disclose how to carry out any such study. Dietzen et al. realistically teach only how to prepare a single liquid standard or calibration solution for use in such a study. Thus, the examiner's statement about what is relied on in Dietzen et al. is not based on the actual disclosure of that reference, nor is it of much relevance to Applicants' claims, which are directed to specific processes.

Similarly, the examiner wishes to rely on Smith et al. only for providing that assays for two of TSH, T<sub>3</sub>, T<sub>4</sub> and TBG using antibodies thereto play important roles as biological markers in assessing thyroid function. However, the disclosure of this reference is nowhere near of such breadth; it is limited to a specific assay employing a dual-isotope technique in what appears to be a competitive assay. Here again the examiner over-generalizes what the reference actually teaches.

When one considers the actual disclosures of these references, it is clear that, as stated previously, they do not provide information that is relevant to the processes that are claimed in this application.

#### CONCLUSION

In view of the foregoing, Applicants submit that the claims under examination are allowable and request issuance of a Notice of Allowance in this Application.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned.

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PATENT

Respectfully submitted,

Joel G. Ackerman  
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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>		Application Number	09/548,883
		Filing Date	April 13, 2000
		First Named Inventor	Watkins, Michael I.
		Art Unit	1641
		Examiner Name	Gabel, G.
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ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input checked="" type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <ul style="list-style-type: none"><li>• Return Postcard</li><li>• Request For Correction Of Inventorship UNDER 37 C.F.R. 1.48(a)</li><li>• Consent Of Assignee To Addition Of Inventor And Certification Of Title (37 CFR 1.48(b)(4) and 37 CFR 3.73(b))</li><li>• Statement of Added Inventor</li><li>• COPY of Assignment as submitted to Assignment Branch for recordation</li><li>• ADS</li></ul>
Remarks		The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual	Townsend and Townsend and Crew LLP Joel G. Ackerman Reg. No. 24,307
Signature	
Date	May 24, 2004

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